

Patent Law

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Monday, March 28, 2016

Class 16 – Patentable subject matter I:
introduction; products of nature

Recap

Recap

- Utility overview
- Operability
- Beneficial utility
- Practical or specific utility

Today's agenda

Today's agenda

- Overview of patentable subject matter
- Products of nature

PSM overview

PSM overview

→ 3+1 core requirements for patentability

- Utility (§ 101)
- Novelty (§ 102)
- Nonobviousness (§ 103)
- Patentable subject matter (§ 101)

(Post-AIA) 35 U.S.C. § 101 — Inventions patentable

Whoever invents or discovers any **new** and **useful process, machine, manufacture, or composition of matter**, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

PSM overview

- Like utility, not usually disputed
 - Most things clearly fall within “process, machine, manufacture, or composition of matter”
 - Issues arise in a few specific areas
- But important when it does come up

PSM overview

- The practical inquiry
 - Step 1: Is it a process, machine, manufacture, or composition of matter?
 - Step 2: If so, does it fall within an implicit exception as a law of nature, physical phenomenon, or abstract idea?

PSM overview

- Step 1: Is it a process, machine, manufacture, or composition of matter?
- Usually this is pretty simple
 - Few things cannot be conceived as either a physical thing or a process

PSM overview

- Step 1: Is it a process, machine, manufacture, or composition of matter?
- Law of gravity?
 - Law of continental drift?
 - Idea of strict liability?
 - New mineral or plant I find in nature?

PSM overview

- Step 2: If so, does it fall within an implicit exception as a law of nature, physical phenomenon, or abstract idea?
 - This is where all the interesting cases are

PSM overview

- Federal Circuit's history:
 - Over time, the exception for laws of nature, physical phenomena, and abstract ideas was read more and more narrowly
 - Federal Circuit adopted a test for PSM: whether a patent claimed something with a "useful, concrete, and tangible result"
 - Then, Federal Circuit adopted the "machine or transformation" test: whether the patent claim is implemented by a machine or transforms an article

PSM overview

- Since 2010, four big Supreme Court cases:
- *Bilski v. Kappos* (2010) – method of hedging risk in a commodities transaction
 - *Mayo v. Prometheus* (2012) – method of determining the correct dose of a drug
 - *Ass'n for Molecular Pathology v. Myriad Genetics* (2013) – isolated DNA and complementary DNA
 - *Alice Corp. v. CLS Bank* (2014) – system for mitigating settlement risk

PSM overview

- These cases have had a transformative effect on patentable subject matter
- *Mayo* and *Myriad*: biotech, medicine, pharmaceuticals
 - *Bilski* and (especially) *Alice*: business methods and computer software

PSM overview

→ The policy question:

- Do these cases add anything valuable that the “new and useful” limitations do not?
- This is one of the big debates in patent law

Products of nature

Diamond v. Chakrabarty

→ Technology?

Diamond v. Chakrabarty

→ Technology?

- New bacteria that can break down crude oil
- Takes a preexisting bacteria and inserts two preexisting plasmids that break down hydrocarbons
- Combination never existed before

Diamond v. Chakrabarty

- Three kinds of claims:
 - Process of making bacteria
 - Inoculum of straw, water, and bacteria
 - Bacteria itself
- Why are the first two not good enough?

Diamond v. Chakrabarty

- Step 1: is this a process, machine, manufacture, or composition of matter?

Diamond v. Chakrabarty

- Step 1: is this a process, machine, manufacture, or composition of matter?
- Court (page 72): “production of articles for use from raw materials or prepared materials by giving to those materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery”

Diamond v. Chakrabarty

- Step 1: is this a process, machine, manufacture, or composition of matter?
- Court (page 72): “composition[] of two or more substances and ... all composite articles, whether they be the result of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids”

Diamond v. Chakrabarty

→ “His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity ‘having a distinctive name, character [and] use.’” (bottom page 72)

Diamond v. Chakrabarty

→ Is there anything physical that doesn't qualify as a “composition of matter”?

Diamond v. Chakrabarty

- Is there anything physical that doesn't qualify as a "composition of matter"?
- "two or more substances"
 - Maybe an element?
 - But, a mixture of quarks?

Diamond v. Chakrabarty

- The statutory-interpretation question: what to make of plant patents?
- Three kinds of patents: utility patents; design patents; plant patents
 - Why would plant patents tell us anything about bacteria?

Diamond v. Chakrabarty

- The statutory-interpretation question: what to make of plant patents?
- Two ways to read the different kinds of patents:
 - Designed to be wholly separate, or
 - Designed to cover specific domains, but can overlap when appropriate

Diamond v. Chakrabarty

- The statutory-interpretation question: what to make of plant patents?
 - Court: plant patents do not implicitly limit § 101
 - So the basic rule of this case: everything made by man is patentable
 - This is the general rule pre-2010

Funk Brothers

→ Technology?

Funk Brothers

→ Technology?

- Leguminous plants (peanuts, peas, soybeans) can absorb nitrogen from the air, but only if certain bacteria is present
- Each plant needs a different species, but you can't combine them because they inhibit each other
- Bond discovered which bacteria don't inhibit each other and figured out how to combine them

Funk Brothers

→ What was a natural phenomenon?

Funk Brothers

→ What was a natural phenomenon?

- Bacteria existed
- Bacteria inhibit each other
- Specific combinations of bacteria wouldn't inhibit each other

Funk Brothers

→ What did Bond invent?

Funk Brothers

→ What did Bond invent?

- He discovered these properties
- Put together the bacteria that wouldn't inhibit each other
- So invented a specific combination that wouldn't inhibit each other

Funk Brothers

- So the patent covers a natural phenomenon, plus a trivial application of that phenomenon
 - Thus, it is a discovery, not an invention
 - Carved out of § 101 as a natural phenomenon
 - **We will see this reasoning again**

Funk Brothers

- What's the difference between *Chakrabarty* and *Funk Brothers*?

Funk Brothers

- What's the difference between *Chakrabarty* and *Funk Brothers*?
- Chakrabarty made something that had never existed before
 - But: Chakrabarty just combined existing plasmids with existing bacteria
 - And: Bond invented a new combination of different bacteria
 - Can we reconcile them?

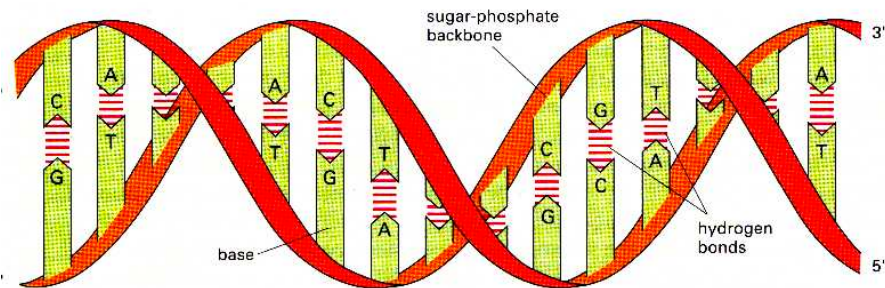
Myriad

- Technology?

Myriad

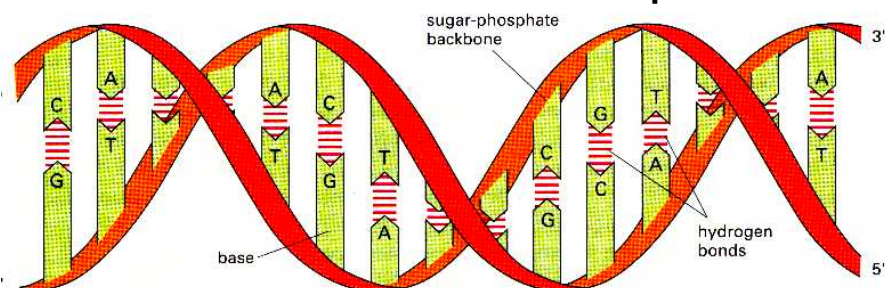
→ Technology?

- Isolated DNA
- Complementary DNA

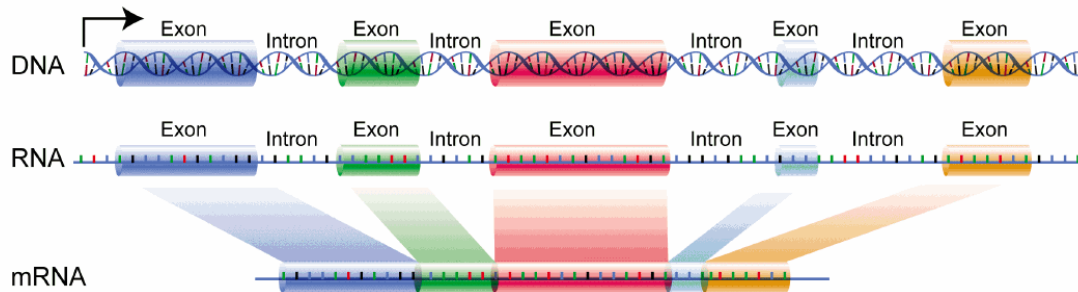


Myriad

- Single chromosome: 80–110,000,000 base pairs
- Isolated DNA: 80,000 base pairs
- cDNA: 5,000–10,000 base pairs



Myriad



Myriad

→ *Parke-Davis & Co. v. HK Mulford & Co.*, S.D.N.Y. 1911 (L. Hand, J.)

- Isolated adrenaline is patentable
- “Takamine was the first to **make it available for any use** by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became **for every practical purpose a new thing commercially and therapeutically.**”

Myriad

- *Parke-Davis & Co. v. HK Mulford & Co.*, S.D.N.Y. 1911 (L. Hand, J.)
 - This was considered good law for 100+ years
 - PTO guidelines, Federal Circuit cases, &c
 - E.g., purified insulin was patented

Myriad

- Unanimous Supreme Court:
isolated DNA is not patentable;
cDNA is patentable
 - isolated DNA appears in nature
 - cDNA does not
- Are you persuaded?

Myriad

- What steps are taken to make isolated DNA?
- What steps are taken to make cDNA?

Myriad

- Don't isolated DNA and cDNA result in molecules that don't exist in nature?

Myriad

- Don't isolated DNA and cDNA result in molecules that don't exist in nature?
- Court: "Myriad's claims are **simply not expressed in terms of chemical composition**, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the **genetic information** encoded in the BRCA1 and BRCA2 genes." (supp. 29)

Myriad

- Don't isolated DNA and cDNA result in molecules that don't exist in nature?
- Court: "...creation of a cDNA sequence from mRNA results in an **exons-only molecule that is not naturally occurring**. ... [T]he lab technician **unquestionably creates something new** when cDNA is made." (supp. 30)

Myriad

→ What do you make of settled expectations? People had relied on these patents for 100 years...

Myriad

→ What do you make of settled expectations? People had relied on these patents for 100 years...

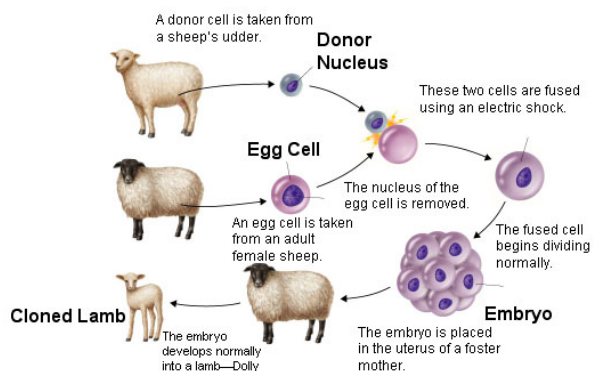
- Court brushes by it because the government now argued it was wrong to do so
- Also, reliance interests are best addressed to Congress
- But, are they?

Roslin Institute

→ Technology?

Roslin Institute

→ Technology?
• Cloning a sheep!



Roslin Institute

→ **Claims:**

- The somatic method of cloning mammals
- The individual cloned animals

Roslin Institute

→ **So do the clones exist in nature?**

Roslin Institute

- So do the clones exist in nature?
 - In one sense, no, they're manmade
 - In another sense, they're identical to the prior-art normal sheep


Roslin Institute

- So do the clones exist in nature?
 - “[in *Chakrabarty*,] the Court held that the modified bacterium was patentable because it was ‘new’ with ‘*markedly different characteristics from any found in nature* and one having the potential for significant utility.’” (supp. 34)

Roslin Institute

→ So do the clones exist in nature?

- “However, Dolly herself is an exact genetic replica of another sheep and does not possess ‘markedly different characteristics from any [farm animals] found in nature.’” (supp. 34)

<i>Chakrabarty</i>	new bacteria	made from of existing bacteria and existing plasmid	patentable
<i>Funk Brothers</i>	new combination of bacteria	made from existing bacteria	not patentable
<i>Myriad</i>	new isolated DNA	made from existing genes	not patentable
<i>Myriad</i>	new cDNA	made from existing genes	patentable
<i>Roslin</i>	new cloned sheep 	made from existing sheep	not patentable

Bottom line (for now)

- If you create something that didn't exist in nature, it's patentable
 - Bacteria in *Chakrabarty*
 - cDNA in *Myriad*
- But if you purify something, or separate pieces, or bundle pieces, or recreate something that previously existed, probably not patentable
 - Bacteria combination in *Funk Brothers*
 - Isolated DNA in *Myriad*
 - Cloned sheep in *Roslin Institute*

Next time

Next time

- Patentable subject matter:
business methods, software, and
abstract ideas